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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,768	12/05/2003	Peter M. Bonutti	2500DV2CN2DV3CN5	3380

7590 07/28/2005

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EXAMINER

THALER, MICHAEL H

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/729,768	Applicant(s) BONUTTI, PETER M.	
	Examiner Michael Thaler	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-21 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) 23-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-21 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/24/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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Claims 23-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on Feb. 18, 2005.

Claims 15-18, 20 and 26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jakubczak (4,651,717). Jakubczak discloses shaft 214 and inflatable bladder 201 which has a conical shape when inflated. The Jakubczak bladder, upon inflation, is inherently capable of creating a working space for the following reasons. The movement of the inflated bladder (by pushing it with an instrument for example, would further separate adjacent layers of tissue and create a working space. Alternatively, the further inflation of a partially inflated bladder would further separate adjacent layers of tissue and create a working space. The term "upon inflation" is broad enough to include partial inflation. Alternatively, it would have been obvious that the Jakubczak bladder, upon inflation, is capable of creating a working space for the reasons set forth above. As to claim 16, the inflatable bladder 201 in the figure 7 embodiment

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does not stretch (at least in the lateral direction) since it is located on mesh 700 which apparently does not stretch. As to claim 26, longitudinal movement of the inflatable bladder would inherently separate adjacent layers of tissue.

Claims 15-21 and 26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sheldon (3,417,745). Sheldon, in figure 3, discloses shaft 56 and inflatable bladder 57 which has an eccentric shape upon inflation. Alternatively, the inflatable bladder 57 in figure 4 has the shape of a wedge since it tapers in the proximal direction. The Sheldon device creates a working space (col. 8, line 74 to col. 9, line 23. Alternatively, it would have been obvious that the Sheldon device creates a working space since it separates adjacent layers of tissue. As to claim 16, Mylar (col. 8, lines 55-58) does not stretch when fully inflated. As to claim 19, shaft 56 is rigidified when attached to rigid shaft 2 (col. 2, lines 39-40 and 60-63). As to claim 21, Sheldon discloses cannula 5.

Applicant's arguments filed July 1, 2005 have been fully considered but they are not persuasive. The allegation that Jakubczak fails to disclose "an inflatable bladder disposed at the distal end of the shaft" is not well taken. Jakubczak

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discloses an inflatable bladder 201 disposed at the distal end of the shaft 214. Further, the bladder 201, upon inflation, is capable of capable of separating adjacent layers of tissue and creating a working space for the reasons set forth above.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

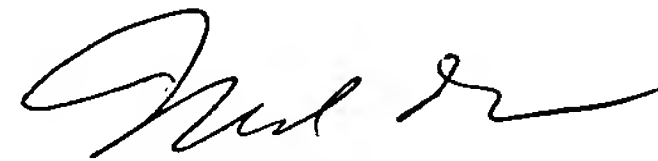
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael

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Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

mht
7/26/05



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731